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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,954      | 08/07/2001  | Beka Solomon         | SOLOMON2C           | 5281             |

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                            |                     |  |
|------------------------------|----------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>     | <b>Applicant(s)</b> |  |
|                              | 09/830,954                 | SOLOMON ET AL.      |  |
|                              | <b>Examiner</b>            | <b>Art Unit</b>     |  |
|                              | Christopher Nichols, Ph.D. | 1647                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-121 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-26 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least one epitope of an aggregating protein associated with plaque formation and said display vehicle wherein said display vehicle is a **virus**.

Group 2, claim(s) 1-5, 12-18, 25, and 26 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least one epitope of an aggregating protein associated with plaque formation and said display vehicle wherein said display vehicle is a **bacteria**.

Group 3, claim(s) 1-5, 12-18, 25, and 26 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least one epitope of an aggregating protein associated with plaque formation and said display vehicle wherein said display vehicle is a **polypeptide carrier**.

Group 4, claim(s) 27-39 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide wherein said display vehicle is a **virus**.

Group 5, claim(s) 27-31, 38, and 39 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide wherein said display vehicle is a **bacteria**.

Group 6, claim(s) 27-31, 38, and 39 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide wherein said display vehicle is a **polypeptide carrier**.

Group 7, claim(s) 40-52 (each in part), drawn to a method of preparing a display vehicle for treating a plaque forming disease, the method comprising the step of genetically modifying a genome of a display vehicle by inserting therein a polynucleotide sequence wherein said display vehicle is a **virus**.

Group 8, claim(s) 40-44, 51, and 52 (each in part), drawn to a method of preparing a display vehicle for treating a plaque forming disease, the method comprising the step of genetically modifying a genome of a display vehicle by inserting therein a polynucleotide sequence wherein said display vehicle is a **bacteria**.

Group 9, claim(s) 53-66 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least an immunological portion of an antibody said display vehicle wherein said display vehicle is a **virus**.

Group 10, claim(s) 53-59 and 66 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least an immunological portion of an antibody said display vehicle wherein said display vehicle is a **bacteria**.

Group 11, claim(s) 53-59 and 66 (each in part), drawn to a method of treating a plaque forming disease comprising the steps of displaying polypeptide on a display vehicle, said polypeptide representing at least an immunological portion of an antibody said display vehicle wherein said display vehicle is a **polypeptide carrier**.

Group 12, claim(s) 67-79 (each in part), drawn to an agent for treating a plaque forming disease comprising a display vehicle displaying a polypeptide representing at least an immunological portion of an antibody wherein said agent is a **virus**.

Group 13, claim(s) 67-72 and 79 (each in part), drawn to an agent for treating a plaque forming disease comprising a display vehicle displaying a polypeptide representing at least an

immunological portion of an antibody wherein said agent is a **bacteria**.

Group 14, claim(s) 67-72 and 79 (each in part), drawn to an agent for treating a plaque forming disease comprising a display vehicle displaying a polypeptide representing at least an immunological portion of an antibody wherein said agent is a **polypeptide carrier**.

Group 15, claim(s) 80-91 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide representing at least an immunological portion of an antibody wherein said display vehicle is a **virus**.

Group 16, claim(s) 80-84 and 91 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide representing at least an immunological portion of an antibody wherein said display vehicle is a **bacteria**.

Group 17, claim(s) 80-84 and 91 (each in part), drawn to a pharmaceutical composition for treating a plaque forming disease comprising an effective amount of a display vehicle displaying a polypeptide representing at least an immunological portion of an antibody wherein said display vehicle is a **polypeptide carrier**.

Group 18, claim(s) 92-103 (each in part), drawn to a method of preparing a display vehicle for treating a plaque forming disease, the method comprising the step of genetically modifying a genome of a display vehicle by inserting therein a polynucleotide sequence wherein said display vehicle is a **virus**.

Group 19, claim(s) 92-96 and 103 (each in part), drawn to a method of preparing a display vehicle for treating a plaque forming disease, the method comprising the step of genetically modifying a genome of a display vehicle by inserting therein a polynucleotide sequence wherein said display vehicle is a **bacteria**.

Group 20, claim(s) 92-96 and 103 (each in part), drawn to a method of preparing a display vehicle for treating a plaque forming disease, the method comprising the step of genetically modifying a genome of a display vehicle by inserting therein a polynucleotide sequence wherein said display vehicle is a **polypeptide carrier**.

Group 21, claim(s) 104-114 (each in part), drawn to a method of introducing a display vehicle lacking an engineered targeting moiety into a brain of a recipient wherein said display vehicle is a **virus**.

Group 22, claim(s) 104, 105, and 111-114 (each in part), drawn to a method of introducing a display vehicle lacking an engineered targeting moiety into a brain of a recipient wherein said display vehicle is a **bacteria**.

Group 23, claim(s) 104, 105, and 111-114 (each in part), drawn to a method of introducing a display vehicle lacking an engineered targeting moiety into a brain of a recipient wherein said display vehicle is a **polypeptide carrier**.

Group 24, claim(s) 115-117, drawn to a polypeptide comprising at least an immunological portion of an antibody.

Group 25, claim(s) 118-121, drawn to a method of detecting a presence or an absence of a prion protein in a biological sample.

4. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups 1-25 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group 1 is a viral display vehicle which is shown by Frenkel *et al.* (1998) "N-terminal EFRH sequence of Alzheimer's  $\beta$ -amyloid peptide represents the epitope of its anti-aggregating antibodies." Journal of Neuroimmunology 88: 85-90 to lack novelty or inventive step as Frenkel *et al.* teaches a phage clone displaying a peptide that has anti-aggregating properties (Table 1) and does not make it a contribution over the prior art. Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.



5. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. Early onset Alzheimer's disease
- b. Late onset Alzheimer's disease
- c. Presymptomatic Alzheimer's disease
- d. SAA amyloidosis
- e. Hereditary Icelandic syndrome
- f. Senility
- g. Multiple myeloma

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 15, 28, 41, 55, 68, 81, and 93 are generic.

**7. If applicant selects any one of Inventions 1-20, one species from the plaque forming disease group must be chosen to be fully responsive.**

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. This application contains claims directed to the following patentably distinct species of the claimed invention:

- h. Scrapie
- i. Bovine spongiform encephalopathy (BSE)
- j. Kuru
- k. Creutzfeldt-Jacob Disease (CJD)
- l. Gerstmann-Streussler-Sheinker Disease (GSS)
- m. Fatal familial insomnia (FFI)

12. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3, 16, 29, 42, 56, 69, 82, and 94 are generic.

**13. If applicant selects any one of Inventions 1-20, one species from the plaque forming disease group must be chosen to be fully responsive.**

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. This application contains claims directed to the following patentably distinct species of the claimed invention:

- n. Beta-amyloid
- o. Serum amyloid A
- p. Cystatin C
- q. IgG kappa light chain
- r. Prion protein

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4, 17, 30, 43, 57, 70, 83, and 95 are generic.

**19. If applicant selects any one of Inventions 1-20, one species from the aggregating protein group must be chosen to be fully responsive.**

20. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

22. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

23. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

24. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Elizabeth C. Kemmerer*

CJN  
September 8, 2003

ELIZABETH KEMMERER  
PRIMARY EXAMINER